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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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07/09/2001

Susan Hardin

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09/18/2002

ROBERT W STROZIER, PLLC

2925 BRIARPARK, SUITE 930

HOUSTON, TX 77042

EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/18/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,782

Applicant(s)

HARDIN ET AL.

Examiner

Carolyn L Smith

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 24-33 have been renumbered 25-34.

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, drawn to a composition, classified in class 435, subclass 183. If this Group is elected then the below summarized specie and subspecie election is required.
- II. Claims 25-26, drawn to a single molecule sequencing apparatus, classified in class 702, subclass 20.
- III. Claims 27-28, drawn to a mutant *Taq* polymerase, classified in class 435, subclass 183.
- IV. Claim 29, drawn to a system for retrieving stored information, classified in class 700, subclass 1.
- V. Claims 30-31, drawn to a system and method for determining molecular sequence, classified in class 700, subclasses 11 and 20, respectively.

- VI. Claim 32, drawn to a method of sequencing an individual nucleic acid molecule or numerous individual molecules in parallel, classified in class 702, subclass 19.
- VII. Claim 33, drawn to a gamma-phosphate modified nucleoside, classified in class 536, subclass 22.1.
- VIII. Claim 34, drawn to a primer sequence, classified in class 536, subclass 24.33. If this Group is elected then the below summarized sequence election is also required.

Sequence Election Requirement Applicable to Group VIII:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C.

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121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

Specie Election Requirement for Group I:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: a polymerizing agent which is a polymerase

Specie B: a polymerizing agent which is a reverse transcriptase

If Specie A is selected:

Subspecie A: a polymerase which is *Taq* DNA polymerase I

Subspecie B: a polymerase which is T7 DNA polymerase

Subspecie C: a polymerase which is Sequenase

Subspecie D: a polymerase which is the Klenow fragment from *E.coli* DNA polymerase

I

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims in Group I are generic to the above species. This distinctness or independence of a polymerase versus a reverse transcriptase

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as well as *Taq* DNA polymerase I versus T7 DNA polymerase versus Sequenase versus the Klenow fragment from *E.coli* DNA polymerase I is described below.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groupings [I-II and IV-VI]; [I (polymerase specie, *Taq* DNA

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(polymerase specie, Sequenase subspecie)]; [I (polymerase specie, Klenow fragment from *E. coli* DNA polymerase I subspecie)]; [I (reverse transcriptase specie)]; [III]; [VII]; and [VIII] are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I-II and IV-VI, the critical feature is a composition. For Group [I (polymerase specie, *Taq* DNA polymerase I subspecie)], the critical feature is *Taq* DNA polymerase I. For Group [I (polymerase specie, T7 DNA polymerase subspecie)], the critical feature is T7 DNA polymerase. For Group [I (polymerase specie, Sequenase subspecie)], the critical feature is Sequenase. For Group [I (polymerase specie, Klenow fragment from *E. coli* DNA polymerase I subspecie)], the critical feature is the Klenow fragment. For Group [I (reverse transcriptase specie)], the critical feature is reverse transcriptase. For Group III, the critical feature is a mutant *Taq* polymerase. For Group VII, the critical feature is a nucleoside. For Group VIII, the critical feature is a primer sequence. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the nine Groupings [I-II and IV-VI]; [I (polymerase specie, *Taq* DNA polymerase I subspecie)]; [I (polymerase specie, T7 DNA polymerase subspecie)]; [I (polymerase

DNA polymerase I subspecie)]; [I (reverse transcriptase specie)]; [III]; [VII]; and [VIII] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I-II and IV-VI are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition of Group I may be utilized in distinct usages as needed in Group II in a single molecule sequencing apparatus, in a system for retrieving stored information as in Group IV, in a system and method for determining molecular sequence information as in Group V, in a method of sequencing an individual nucleic acid molecule or numerous individual molecules in parallel as in Group VI, or alternatively, in cell growth inhibition studies. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

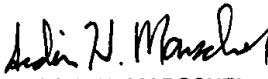
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 9 A.M. to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 10, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER